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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/006,542      | 11/30/2001  | John D. McNeish      | PCI0897ADAM         | 1000             |

7590 10/28/2002  
Gregg C. Benson  
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EXAMINER

BERTOGLIO, VALERIE E

ART UNIT PAPER NUMBER

1632

DATE MAILED: 10/28/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/006,542

Applicant(s)

MCNEISH ET AL.

Examiner

Valarie Bertoglio

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Election/Restriction*.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to a genetically modified animal with a disruption in the RAMP1 gene, classified in class 800, subclass 14.
- II. Claims 1-3, drawn to drawn to a genetically modified animal with a disruption in the RAMP3 gene, classified in class 800, subclass 14.
- III. Claims 4-5, drawn to a genetically modified animal with a disruption in the RAMP2 gene, classified in class 800, subclass 14.
- IV. Claims 6-8, drawn to a genetically modified animal cell with a disruption in the RAMP1 gene, classified in class 435, subclass 325.
- V. Claims 6-8, drawn to a genetically modified animal cell with a disruption in the RAMP2 gene, classified in class 435, subclass 325.
- VI. Claims 6-8, drawn to a genetically modified animal cell with a disruption in the RAMP3 gene, classified in class 435, subclass 325.
- VII. Claim 9, drawn to a membrane preparation derived from a genetically-modified animal cell comprising a disrupted RAMP1 gene, classified in class 800, subclass 3.
- VIII. Claim 9, drawn to a membrane preparation derived from a genetically-modified animal cell comprising a disrupted RAMP2 gene, classified in class 800, subclass 3.
- IX. Claim 9, drawn to a membrane preparation derived from a genetically-modified animal cell comprising a disrupted RAMP3 gene, classified in class 800, subclass 3.

- X. Claims 10 and 11, drawn to a method of treating a disorder using a RAMP1 modulator, classified in various classes and subclasses.
- XI. Claim 12, drawn to a method of identifying RAMP1 modulators using a mammalian cell from the female or male reproductive tract, classified in class 530, subclass 350.
- XII. Claim 12, drawn to a method of identifying RAMP2 modulators using a mammalian spermatogenic cell, classified in class 530, subclass 350.
- XIII. Claim 12, drawn to a method of identifying RAMP3 modulators using a mammalian cell from the caudate putamen, the laterodorsal thalamic region of the cerebrum, or the male reproductive tract, classified in class 530, subclass 350.
- XIV. Claims 13-14, drawn to a method of identifying an agent that modulates RAMP1 expression comprising contacting the agent with a mammalian cell from the female or male reproductive tract, or the skin, that expresses a coding sequence under the control of RAMP1 regulatory sequences, classified in 530, subclass 350.
- XV. Claim 13-14, drawn to a method of identifying an agent that modulates RAMP2 expression comprising contacting the agent with a mammalian spermatogenic cell that expresses a coding sequence under the control of RAMP2 regulatory sequences, classified in class 530, subclass 350.
- XVI. Claim 13-14, drawn to a method of identifying an agent that modulates RAMP3 expression comprising contacting the agent with a mammalian cell from the female or male reproductive tract, or the skin, that expresses a coding sequence

under the control of RAMP3 regulatory sequences, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are patentably distinct because they are directed to genetically distinct animals. The structure of each group differs from that of the other. The animal of each group is not necessary for the other. The burden required to search Groups I-III together would be undue.

Invention I and IV-VI are patentably distinct because, the transgenic animal of Group I can be used as an in vivo disease model while the cells can be used in in vitro assays for modulators of RAMP1 (Group IV), RAMP2 (Group V), or RAMP3 (Group VI). The protocols and reagents required for the transgenic and the cells are materially distinct and separate. The burden required to search Groups I and IV-VI together would be undue.

Invention I and VII-IX are patentably distinct because, the transgenic animal of Group I can be used as an in vivo disease model while the membrane preparations can be used to isolate protein. The protocols and reagents required for the transgenic and the membrane preparations are materially distinct and separate. The transgenic does not require the membrane preparation and the membrane preparation does not require the transgenic. The burden required to search Groups I and VII-IX together would be undue.

Invention I and X are patentably distinct because, the transgenic animal of Group I can be used as an in vivo disease model while the methods can be used to treat disease. The protocols and reagents required for the transgenic and the methods of treatment are materially distinct and separate. The transgenic does not require the treatment and the treatment does not require the transgenic. The burden required to search Groups I and X together would be undue.

Invention I and Inventions XI-XIII are patentably distinct because, the transgenic animal of Group I can be used as an in vivo disease model while the methods of identifying modulators of RAMP1 (Group XI), RAMP2 (Group XII), or RAMP3 (Group XIII) activity can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the transgenic and the methods are materially distinct and separate. The transgenic does not require the methods and the methods do not require the transgenic. The burden required to search Groups I and Groups XI-XIII together would be undue.

Invention I and Inventions XIV-XVI are patentably distinct because, the transgenic animal of Group I can be used as an in vivo disease model while the methods of identifying modulators of RAMP1 (Group XIV), RAMP2 (Group XV), or RAMP3 (Group XVI) expression can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the transgenic and the methods are materially distinct and separate. The transgenic does not require the methods and the methods do not require the transgenic. The burden required to search Groups I and Groups XIV-XVI together would be undue.

Invention II and IV-VI are patentably distinct because, the transgenic animal of Group II can be used as an in vivo disease model while the cells can be used in in vitro assays for modulators of RAMP1 (Group IV), RAMP2 (Group V), or RAMP3 (Group VI). The protocols and reagents required for the transgenic and the cells are materially distinct and separate. The burden required to search Groups II and IV-VI together would be undue.

Invention II and VII-IX are patentably distinct because, the transgenic animal of Group II can be used as an in vivo disease model while the membrane preparations can be used to isolate protein. The protocols and reagents required for the transgenic and the membrane preparations

are materially distinct and separate. The transgenic does not require the membrane preparation and the membrane preparation does not require the transgenic. The burden required to search Groups II and VII-IX together would be undue.

Invention II and X are patentably distinct because, the transgenic animal of Group II can be used as an in vivo disease model while the methods can be used to treat disease. The protocols and reagents required for the transgenic and the methods of treatment are materially distinct and separate. The transgenic does not require the treatment and the treatment does not require the transgenic. The burden required to search Groups II and X together would be undue.

Invention II and Inventions XI-XIII are patentably distinct because, the transgenic animal of Group II can be used as an in vivo disease model while the methods of identifying modulators of RAMP1 (Group XI), RAMP2 (Group XII), or RAMP3 (Group XIII) activity can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the transgenic and the methods are materially distinct and separate. The transgenic does not require the methods and the methods do not require the transgenic. The burden required to search Group II and Groups XI-XIII together would be undue.

Invention II and Inventions XIV-XVI are patentably distinct because, the transgenic animal of Group II can be used as an in vivo disease model while the methods of identifying modulators of RAMP1 (Group XIV), RAMP2 (Group XV), or RAMP3 (Group XVI) expression can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the transgenic and the methods are materially distinct and separate. The transgenic does not require the methods and the methods do not require the transgenic. The burden required to search Group II and Groups XIV-XVI together would be undue.

Inventions I-III are patentably distinct because they are directed to genetically distinct animals. The structure of each group differs from that of the other. The animal of each group is not necessary for the other. The burden required to search groups I-III together would be undue.

Invention III and IV-VI are patentably distinct because, the transgenic animal of Group III can be used as an in vivo disease model while the cells can be used in in vitro assays for modulators of RAMP1 (Group IV), RAMP2 (Group V), or RAMP3 (Group VI). The protocols and reagents required for the transgenic and the cells are materially distinct and separate. The burden required to search Groups III and IV-VI together would be undue.

Invention III and VII-IX are patentably distinct because, the transgenic animal of Group III can be used as an in vivo disease model while the membrane preparations can be used to isolate protein. The protocols and reagents required for the transgenic and the membrane preparations are materially distinct and separate. The transgenic does not require the membrane preparation and the membrane preparation does not require the transgenic. The burden required to search Groups III and VII-IX together would be undue.

Invention III and X are patentably distinct because, the transgenic animal of Group III can be used as an in vivo disease model while the methods can be used to treat disease. The protocols and reagents required for the transgenic and the methods of treatment are materially distinct and separate. The transgenic does not require the treatment and the treatment does not require the transgenic. The burden required to search Groups III and X together would be undue.

Invention III and Inventions XI-XIII are patentably distinct because, the transgenic animal of Group III can be used as an in vivo disease model while the methods of identifying modulators of RAMP1 (Group XI), RAMP2 (Group XII), or RAMP3 (Group XIII) activity can



be used in vitro to identify drugs for treating disease. The protocols and reagents required for the transgenic and the methods are materially distinct and separate. The transgenic does not require the methods and the methods do not require the transgenic. The burden required to search Group III and Groups XI-XIII together would be undue.

Invention III and Inventions XIV-XVI are patentably distinct because, the transgenic animal of Group III can be used as an in vivo disease model while the methods of identifying modulators of RAMP1 (Group XIV), RAMP2 (Group XV), or RAMP3 (Group XVI) expression can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the transgenic and the methods are materially distinct and separate. The transgenic does not require the methods and the methods do not require the transgenic. The burden required to search Group III and Groups XIV-XVI together would be undue.

Inventions IV-VI are patentably distinct because they are drawn to genetically distinct cells. The structure of each group differs from that of the other. The cell of each group is not necessary for the other and each has a use independent of the other consistent with their distinct genetic structures. The burden required to search Groups IV-VI together would be undue.

Invention IV and VII-IX are patentably distinct because, the cells of Group IV can be used to determine the effects of RAMP1 on gene expression while the membrane preparations can be used to isolate protein. The protocols and reagents required for the cells the membrane preparations are materially distinct and separate. The burden required to search Groups IV and VII-IX together would be undue.

Invention IV and X are patentably distinct because, the cells of Group IV can be used to determine the effects of RAMP1 on gene expression while the methods can be used to treat

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disease. The protocols and reagents required for the cells and the methods of treatment are materially distinct and separate. The transgenic does not require the treatment and the treatment does not require the transgenic. The burden required to search Groups V and X together would be undue.

Invention IV and Inventions XI-XIII are patentably distinct because, the cells of Group IV can be used to determine the effects of RAMP1 on gene expression while the methods of identifying modulators of RAMP1 (Group XI), RAMP2 (Group XII), or RAMP3 (Group XIII) activity can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the cells and the methods are materially distinct and separate. The cells do not require the methods and the methods do not require the cells. The burden required to search Group IV and Groups XI-XIII together would be undue.

Invention IV and Inventions XIV-XVI are patentably distinct because, the cells of Group IV can be used to determine the effects of RAMP1 on gene expression while the methods of identifying modulators of RAMP1 (Group XIV), RAMP2 (Group XV), or RAMP3 (Group XVI) expression can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the cells and the methods are materially distinct and separate. The cells do not require the methods and the methods do not require the cells. The burden required to search Group IV and Groups XIV-XVI together would be undue.

Invention V and VII-IX are patentably distinct because, the cells of Group V can be used to determine the effects of RAMP2 on gene expression while the membrane preparations can be used to isolate protein. The protocols and reagents required for the cells the membrane

preparations are materially distinct and separate. The burden required to search Groups V and VII-IX together would be undue.

Invention V and X are patentably distinct because, the cells of Group V can be used to determine the effects of RAMP2 on gene expression while the methods can be used to treat disease. The protocols and reagents required for the cells and the methods of treatment are materially distinct and separate. The transgenic does not require the treatment and the treatment does not require the transgenic. The burden required to search Groups V and X together would be undue.

Invention V and Inventions XI-XIII are patentably distinct because, the cells of Group V can be used to determine the effects of RAMP2 on gene expression while the methods of identifying modulators of RAMP1 (Group XI), RAMP2 (Group XII), or RAMP3 (Group XIII) activity can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the cells and the methods are materially distinct and separate. The cells do not require the methods and the methods do not require the cells. The burden required to search Group V and Groups XIV-XVI together would be undue.

Invention V and Inventions XIV-XVI are patentably distinct because, the cells of Group V can be used to determine the effects of RAMP2 on gene expression while the methods of identifying modulators of RAMP1 (Group XIV), RAMP2 (Group XV), or RAMP3 (Group XVI) expression can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the cells and the methods are materially distinct and separate. The cells do not require the methods and the methods do not require the cells. The burden required to search Group V and Groups XI-XIII together would be undue.

Invention VI and VII-IX are patentably distinct because, the cells of Group VI can be used to determine the effects of RAMP3 on gene expression while the membrane preparations can be used to isolate protein. The protocols and reagents required for the cells the membrane preparations are materially distinct and separate. The burden required to search Groups VI and VII-IX together would be undue.

Invention VI and X are patentably distinct because, the cells of Group VI can be used to determine the effects of RAMP3 on gene expression while the methods can be used to treat disease. The protocols and reagents required for the cells and the methods of treatment are materially distinct and separate. The cells do not require the treatment and the treatment does not require the cells. The burden required to search Groups VI and X together would be undue.

Invention VI and Inventions XI-XIII are patentably distinct because, the cells of Group VI can be used to determine the effects of RAMP3 on gene expression while the methods of identifying modulators of RAMP1 (Group XI), RAMP2 (Group XII), or RAMP3 (Group XIII) activity can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the cells and the methods are materially distinct and separate. The cells do not require the methods and the methods do not require the cells. The burden required to search Group VI and Groups XI-XIII together would be undue.

Invention VI and Inventions XIV-XVI are patentably distinct because, the cells of Group VI can be used to determine the effects of RAMP3 on gene expression while the methods of identifying modulators of RAMP1 (Group XIV), RAMP2 (Group XV), or RAMP3 (Group XVI) expression can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the cells and the methods are materially distinct and separate. The cells do not

require the methods and the methods do not require the cells. The burden required to search Group VI and Groups XIV-XVI together would be undue.

Inventions VII-IX are drawn to membrane preparations from genetically distinct cells. The structure of each group differs from that of the other. The starting material for each Group is different. The composition of each Group is different. Each Group is not necessary for the other. The burden required to search Groups VII-IX together would be undue.

Invention VII and X are patentably distinct because, the membrane preparation can be used to isolate membrane-bound proteins while the methods can be used to treat disease. The protocols and reagents required for the cells and the methods of treatment are materially distinct and separate. The membrane preparation does not require the treatment and the treatment does not require the membrane preparations. The burden required to search Groups VII and X together would be undue.

Invention VII and Invention XI-XIII are patentably distinct because, the membrane preparation can be used to isolate membrane-bound proteins while the method of identifying modulators of RAMP1 (Group XI), RAMP2 (Group XII), or RAMP3 (Group XIII) activity can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the membrane preparations and the methods are materially distinct and separate. The burden required to search Group VII and Groups XI-XIII together would be undue.

Invention VII and Inventions XIV-XVI are patentably distinct because, the membrane preparation can be used to isolate membrane-bound proteins while the methods of identifying modulators of RAMP1 (Group XIV), RAMP2 (Group XV), or RAMP3 (Group XVI) expression can be used in vitro to identify drugs for treating disease. The protocols and reagents required for

the membrane preparations and the methods are materially distinct and separate. The membrane preparations do not require the methods and the methods do not require the membrane preparations. The burden required to search Group VII and Groups XIV-XVI together would be undue.

Invention VIII and X are patentably distinct because, the membrane preparation can be used to isolate membrane-bound proteins while the methods can be used to treat disease. The protocols and reagents required for the cells and the methods of treatment are materially distinct and separate. The membrane preparation does not require the treatment and the treatment does not require the membrane preparations. The burden required to search Groups VIII and X together would be undue.

Invention VIII and Invention XI-XIII are patentably distinct because, the membrane preparation can be used to isolate membrane-bound proteins while the method of identifying modulators of RAMP1 (Group XI), RAMP2 (Group XII), or RAMP3 (Group XIII) activity can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the membrane preparations and the methods are materially distinct and separate. The burden required to search Group VIII and Groups XI-XIII together would be undue.

Invention VIII and Inventions XIV-XVI are patentably distinct because, the membrane preparation can be used to isolate membrane-bound proteins while the methods of identifying modulators of RAMP1 (Group XIV), RAMP2 (Group XV), or RAMP3 (Group XVI) expression can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the membrane preparations and the methods are materially distinct and separate. The membrane preparations do not require the methods and the methods do not require the membrane

preparations. The burden required to search Group VIII and Groups XIV-XVI together would be undue.

Invention IX and X are patentably distinct because, the membrane preparation can be used to isolate membrane-bound proteins while the methods can be used to treat disease. The protocols and reagents required for the cells and the methods of treatment are materially distinct and separate. The membrane preparation does not require the treatment and the treatment does not require the membrane preparations. The burden required to search Groups IX and X together would be undue.

Invention IX and Invention XI-XIII are patentably distinct because, the membrane preparation can be used to isolate membrane-bound proteins while the method of identifying modulators of RAMP1 (Group XI), RAMP2 (Group XII), or RAMP3 (Group XIII) activity can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the membrane preparations and the methods are materially distinct and separate. The burden required to search Group IX and Groups XI-XIII together would be undue.

Invention IX and Inventions XIV-XVI are patentably distinct because, the membrane preparation can be used to isolate membrane-bound proteins while the methods of identifying modulators of RAMP1 (Group XIV), RAMP2 (Group XV), or RAMP3 (Group XVI) expression can be used in vitro to identify drugs for treating disease. The protocols and reagents required for the membrane preparations and the methods are materially distinct and separate. The membrane preparations do not require the methods and the methods do not require the membrane preparations. The burden required to search Group IX and Groups XIV-XVI together would be undue.

Invention X and Invention XI-XIII are patentably distinct because, the methods can be used to treat disease in vivo while the method of identifying modulators of RAMP1 (Group XI), RAMP2 (Group XII), or RAMP3 (Group XIII) can be used in vitro to identify compounds that alter of RAMP1 (Group XI), RAMP2 (Group XII), or RAMP3 (Group XIII) activity. The protocols and reagents required for the treatment and the methods of identifying modulators are materially distinct and separate. The burden required to search Group X and Groups XI-XIII together would be undue.

Invention X and Inventions XIV-XVI are patentably distinct because, the methods can be used to treat disease in vivo while the methods of identifying modulators of RAMP1 (Group XIV), RAMP2 (Group XV), or RAMP3 (Group XVI) expression can be used in vitro to identify transcription factors. The protocols and reagents required for the treatment and the methods of identifying modulators are materially distinct and separate. The burden required to search Group X and Groups XIV-XVI together would be undue.

Inventions XI-XIII are patentably distinct because they are drawn to methods of identifying modulators of distinct protein activities. Group XI is directed to modulators of RAMP1 activity. Group XII is directed to modulators of RAMP2 activity. Group XIII is directed to modulators of RAMP3 activity. The methods and reagents for each group are distinctly different and comprise different method steps. The starting material for each group is different. Each group is not necessary for the other. The burden required to search Groups XI-XIII together would be undue.

Invention XI and Inventions XIV-XVI are patentably distinct because, the methods of Group XI can be used to identify compounds that interact with RAMP1 while the methods of



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Groups XIV-XVI can be used to identify transcription factors that modulate expression of RAMP1 (Group XIV), RAMP2 (Group XV), or RAMP3 (Group XVI). The protocols and reagents required for the methods Group XI and Groups XIV-XVI are materially distinct and separate. The burden required to search Group XI and Groups XIV-XVI together would be undue.

Invention XII and Inventions XIV-XVI are patentably distinct because, the methods of Group XII can be used to identify compounds that interact with RAMP2 while the methods of Groups XIV-XVI can be used to identify transcription factors that modulate expression of RAMP1 (Group XIV), RAMP2 (Group XV), or RAMP3 (Group XVI). The protocols and reagents required for the methods Group XII and Groups XIV-XVI are materially distinct and separate. The burden required to search Group XII and Groups XIV-XVI together would be undue.

Invention XIII and Inventions XIV-XVI are patentably distinct because, the methods of Group XIII can be used to identify compounds that interact with RAMP3 while the methods of Groups XIV-XVI can be used to identify transcription factors that modulate expression of RAMP1 (Group XIV), RAMP2 (Group XV), or RAMP3 (Group XVI). The protocols and reagents required for the methods Group XIII and Groups XIV-XVI are materially distinct and separate. The burden required to search Group XIII and Groups XIV-XVI together would be undue.

Inventions XIV-XVI are patentably distinct because they are drawn to methods of identifying modulators of the expression of distinct genes. Group XIV is directed to modulators of RAMP1 expression. Group XV is directed to modulators of RAMP2 expression. Group XVI

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is directed to modulators of RAMP3 expression. The methods and reagents for each group are distinctly different and comprise different method steps. The starting material for each group is different. Each group is not necessary for the other. The burden required to search Groups XIV-XVI together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular

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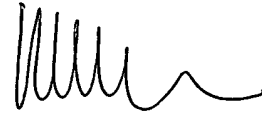
communications and 703-872-9307 for Af

ter Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.



Valarie Bertoglio  
Patent Examiner



MICHAEL C. WILSON  
PATENT EXAMINER